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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,484	10/02/2008	Mark J. Ratain	ARCD:405US/ 10611334	9362
32425 7590 10/21/2010 FULBRIGHT & JAWORSKI L.L.P. 600 CONGRESS AVE. SUITE 2400 AUSTIN, TX 78701			EXAMINER GOLDBERG, JEANINE ANNE	
			ART UNIT 1634	PAPER NUMBER
			NOTIFICATION DATE 10/21/2010	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

aopatent@fulbright.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/591,484	<b>Applicant(s)</b> RATAIN ET AL.	
	<b>Examiner</b> JEANINE A. GOLDBERG	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on 02 October 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

2. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-39, drawn to methods for predicting the level of ABCC2 activity by determining the sequence at position 3972; determining dosage of an ABCC2 substrate for a patient by determining the sequence at position 3972; predicting the risk of irinotecan toxicity based upon the ABCC2 gene and predicting a clearance rate for irinotecan based upon ABCC2 gene position 3972.

Group II, claim(s) 23-39, drawn to directed to predicting risk of irinotecan toxicity by analyzing the SLC01B1 gene and predicting the clearance rate for irinotecan by analyzing position 521 of SLC01B1 gene.

Group III, claim(s) 23-39 are directed to predicting risk of irinotecan toxicity by analyzing the ABCC2 gene and the SLC01B1 gene and predicting the clearance rate for irinotecan by analyzing position 521 of SLC01B1 gene.

Group IV, claim(s) 41-46, drawn to a kit comprising nucleic acid for determining the sequence at position 3972, 1549, -1019, -24, 1249, 34 in intron 27 of the ABCC2 gene.

Group V, claim(s) 41-46, drawn to drawn to a kit comprising at least one nucleic acid for position 388 of SLC01B1 gene.

Group VI, claim(s) 41-46, drawn to kits comprising nucleic acids for the ABCC2 and the SLC01B1 gene.

Further Restriction Requirement

3. Group IV and Group VI are directed to kits comprising numerous combinations of nucleic acids. The claims are directed to numerous different kits recited in the alternative. The language “at least one” and “and/or” requires that one, two, three or any number more up to the 6 recited SNPs are packaged in a kit. For example, a kit requiring SNP of 3972 is different from a kit comprising nucleic acids to the SNP at position 1249. Each nucleic acid is directed to a different position and have a different mode of operation, do not overlap in scope, and they are not obvious variants of one another (see MPEP 806.05(j)). Each of the SNPs are located in different markers, genes and sequences.

The claims further encompass many subcombinations which are disclosed as usable together in a single combination and which are also separately usable. For example, consider the following combinations of “one or more” and “and/or” SNP selected from those disclosed:

Subcombination (A): the SNP at position 3972 and 1549

Subcombination (B): the SNP at position -1019 and -24

Combination (A+B): the SNP at position 3972 and 1549 and -1019 and -24.

Each of the combinations of SNPs are related as subcombinations disclosed as usable together in a single combination. The subcombinations are different if they do

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not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In this case subcombinations (A) and (B) do not overlap in scope and there is no evidence on the record to suggest that they are obvious variants of one another. The subcombinations are separately usable as evidenced by their presentation in the alternative within the claims. Further, subcombination "A" has separate utility such as detecting the SNP, as a marker, or for linkage studies, for examples. So, subcombinations (A) and (B) are different. See MPEP § 806.05(d).

These subcombinations are also different from the combination which comprises them because the combination does not require the particulars of the subcombination as claimed to show novelty or unobviousness and the subcombinations have utility by themselves or in another combination. The fact that the claim encompasses an embodiment which relies on only subcombination (B) is evidence that the details of subcombination (A) are not required for patentability of the combination (A+B), and likewise, the fact that the claim encompasses an embodiment which relies on only subcombination (A) is evidence that the details of subcombination (B) are not required for patentability of subcombination (A+B). The fact that the claim encompasses embodiments which use only subcombination (A) or subcombination (B) is evidence that the subcombinations have utility by themselves.

This example particularly discusses only the combinations (A), (B) and (A+B), but the same analysis could be applied to each of the different subcombinations and combinations set forth in the instant claims.

Each SNP must be searched by a separate query of the electronic databases. See MPEP 808.02(C). Therefore, a search for methods which use each SNP or each combination of SNPs is not co-extensive with methods which use each other SNP or each other combination of SNPs, and subsequently, the search and examination for every SNP and every combination of SNP poses an enormous and serious burden on the examiner.

Applicant is required to select a single invention, ie, a single SNP or a single combination of SNPs required for the claimed kits. The invention may be a single SNP, a combination of more than one SNP but less than all of the disclosed SNPs or a combination of all possible claimed SNPs. However, an election of a single invention, ie, a single SNP or a single combination of SNPs is required. This requirement is predicated on the fact that the nucleic acids for determining each of the SNPs or different combinations of SNPs do not appear obvious over one another. Should applicant traverse on the ground that the different SNPs or different combinations of SNPs are not patentably different over each other, applicant should submit evident or identify such evidence now of record showing the inventions to be obvious variant over each other or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

Applicant is also required to identify which claims read upon the elected invention.

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

4. The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Claim 41, for example, is directed to a kit comprising nucleic acid for determining the sequence at various positions in the ABCC2 and/or SLC01B1 gene. The prior art teaches hexamer kits are useful for amplifying nucleic acids for further detection.

Moreover, the prior art, namely Gerk and Suzuki teaches mutation in the MRP2/ABCC2 gene including -24, 1249, and 3972. Finally, Ito teaches primer pairs for amplifying the MPR2 gene which allow the nucleic acid at the recited positions to be determined. As such, there is no special technical feature that is a contribution over the prior art.

**Joint Inventors**

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

**Notice of Rejoinder**

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the



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above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Nguyen, can be reached on (571)272-0731.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Central Fax Number for official correspondence is (571) 273-8300.

**/Jeanine Goldberg/**  
**Primary Examiner**  
October 18, 2010